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10/565,118	06/19/2006	Janet Bryan	F7720(V)	6151

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EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,118	BRYAN ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) *11 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/5/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 2-11 and 13-15 are pending in this application. Claims 1 and 12 stand canceled.

2. Claims 11 and 13 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/18/08.

3. Claims 2-10, 14, and 15 are examined.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2-8, 10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (WO 03/003981).

The claimed invention is drawn to a method for aiding the cognitive development or cognitive performance of humans having an age of up to 18 years, the method comprising the step of administering to said human by means of an edible composition: 1) a bioavailable iron compound, and a bioavailable zinc compound in a weight ratio of from 2:1 to 5:1, and 2) at least one B vitamin (see claim 14). Applicants have further elected the method wherein the composition further comprises at least one polyunsaturated fatty acid (claim 7).

Smith teaches compositions for improving mental performance comprising B-complex vitamins, minerals, and docosahexaenoic acid (DHA) (a polyunsaturated fatty acid) and wherein the minerals comprise zinc and iron (pages 10-12). Smith teaches that the minerals are in the form of Krebs cycle intermediates, which are "highly absorbable" (page 11, lines 24-26). The amount of zinc present is about 5 mg to about 30 mg (page 12, lines 11-12) and iron may comprise about 1 mg to about 18 mg (page 12, line14).

Smith differs from the claimed invention because it does not explicitly teach Applicant's limitation of having iron and zinc compounds in a weight ration of from 2:1 to 5:1 (claim 14) or 2:1 to 4:1 (claim 6), and it does not explicitly teach the composition is used to aid the cognitive development or cognitive performance of humans having an age of up to 18 years (i.e., children).

However, the weight ranges taught by Smith include iron: zinc weight ratios of 2:1 (e.g., when iron is 10-18 mg and when zinc is 5-9 mg) to 3.6:1 (e.g., when iron is 18 mg and zinc is 5 mg). Furthermore, Smith teaches that "iron deficiency, which exists in a significant number of children with learning disabilities, may be a causative factor for much of the symptomatology associated with such poor cognitive function", and that supplementation with zinc and iron "among other minerals may provide cognitive protective effects, as well as improve memory, communication, and understanding" (page 10, lines 23-28).

It would have been obvious at the time the invention was made to use the composition of Smith having an iron: zinc weight ratio of 2:1 to 3.6:1 for aiding the

cognitive development or cognitive performance of humans having an age of up to 18 years, with a reasonable expectation of success.

One skilled in the art of developing compositions for aiding cognitive development or performance of humans would have been motivated to choose the specified amounts and weight ratios of iron and zinc within the amount ranges taught by Smith as a matter of routine optimization, in order to achieve the expected results of improved mental performance as taught by Smith. Furthermore, one skilled in the art would have been motivated to use the composition of Smith for aiding the cognitive development or cognitive performance of humans having an age of up to 18 years because Smith teaches that it is already known that iron deficiencies in children may be the cause of poor cognitive function, and supplementation with iron and zinc may provide cognitive protective effects against such deficiencies (page 10, lines 23-28).

With respect to claim 2, Smith teaches that iron may be present in an amount of about 1 mg to about 18 mg (page 12, line14). This is encompassed by Applicant's amount of 0.1 to 30 mg.

With respect to claim 3, Smith teaches that typical iron compounds that may be present in the composition are ferrous fumorate , ferrous gluconate, ferrous, sulfate, and iron polysaccharide; this is encompassed by Applicant's listing of iron compounds, which includes ferrous carboxylate salts, ferrous inorganic compounds, and iron-sugar-carboxylate compounds.

With respect to claim 4, Smith teaches that the amount of zinc present is about 5 mg to about 30 mg (page 12, lines 11-12). This is comparable to Applicant's amount of

0.5 to 20 mg, and it would have been obvious to determine workable and/or optimal amounts of zinc present as a matter of routine experimentation.

With respect to claim 5, Smith teaches that zinc may be present in the composition bound to picolinate, citrate, acetate, gluconate, glycine, monomethionine, chelates and/or ascorbate form. This is encompassed by Applicant's listing of inorganic zinc salts, zinc carboxylate salts and chelated zinc compounds.

With respect to claim 7, Smith teaches that the polyunsaturated fatty acid DHA is present in the composition (pages 15-16).

With respect to claim 8, Smith teaches that DHA is present from about 20 mg to about 200 mg in the composition; this is encompassed by Applicant's amount of up to 2 g per serving.

With respect to claim 10, Smith teaches that the B vitamins B6 and B12 are present in the composition (pages 7 and 8).

With respect to claim 15, Smith teaches that the composition may be in liquid form, suitably with flavored emulsions with edible oils (page 24, lines 24-27). This is encompassed by Applicant's definition of a "food composition" which comprises at least one fat (page 15, lines 17-19 of Applicant's specification).

Response to Arguments

In Applicant's remarks filed 1/18/08, Applicants argued that WO '981 does not appear to mention improving cognitive function in children, and that the development of children and their brain is very specific and is accompanied by unique problems and

challenges. This statement is not found to be persuasive because Applicants have not provided any objective evidence showing that the development of children and their brain is "unique", or that the composition of Smith (which is not limited to a specific group of humans) would not work in improving the mental performance of children. Furthermore, Smith teaches that "iron deficiency, which exists in a significant number of children with learning disabilities, may be a causative factor for much of the symptomatology associated with such poor cognitive function", and the supplementation with zinc and iron "among other minerals may provide cognitive protective effects, as well as improve memory, communication, and understanding" (page 10, lines 23-28).

Applicants also argued that fortifying a foodstuff with iron and zinc is not straightforward because of the restraints of food legislation, competition between zinc and iron for uptake in the bloodstream, and a minimum level of zinc required with iron. This is not found to be persuasive because acceptable weight ranges for zinc and iron are already taught by Smith (page 12, lines 11-16), and Smith specifically teaches that problems with competition for absorption are overcome by using non-competitive sources of minerals called Krebs Cycle intermediates (see page 11, lines 20-27 and examples of mineral forms on page 12).

Applicants finally argued that the two facts of iron concentration in blood going up and cognitive performance being enhanced, are surprising and are an indication of non-obviousness. This is not found to be persuasive because the results are, in fact, not surprising, since Smith already teaches that the disclosed compositions improve mental performance. Additionally, Applicants have not compared the iron: zinc weight ratio of

the claimed invention with the closest prior art; therefore, the Examiner cannot conclude if the iron: zinc weight ratio of the claimed invention produces unexpected results are not.

It is the Examiner's position that the results presented in the article accompanying the remarks filed 1/18/08 are, in fact, expected, because the data presented only shows that the composition produces the expected result of improving mental performance as taught by Smith, and Applicants have not presented any objective evidence comparing the claimed invention with the closest prior art to show that the composition of the claimed invention produces results that are unexpected.

6. Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive.

Applicants argue that Smith is clearly teaching a higher amount of zinc in comparison with iron, citing the ranges of zinc and iron taught by Smith (5-30 mg and 1-18 mg, respectively), and the example of Smith which teaches more zinc than iron present (page 21 Table 1). Applicants further argue that one of ordinary skill in the art would not have been led by Smith to employ more iron than zinc. Applicants also argue that one would have been dissuaded to use amounts of zinc less than the amounts of iron, since Smith teaches that quantity of zinc and other nutrients is key, and because the range of amounts for zinc is higher than the range of amounts for iron.

These arguments are not persuasive because Smith still generally teaches amounts of iron and zinc in ranges comparable to those of the claimed invention (e.g.,

when iron is 10-18 mg and when zinc is 5-9 mg), and one skilled in the art would be able to optimize said amounts of iron and zinc within the ranges taught by Smith through routine experimentation to achieve the expected result of improving mental performance. Therefore, a *prima facie* case of obviousness exists. Furthermore, Applicants have not shown that the particular weight ratios claimed in the claimed invention produce results which are unexpected from those of the closest prior art, for reasons stated above (see pages 6 and 7 of this Office action).

Therefore, it is the Examiner's position that the claims are rendered obvious.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, WO 03/003981 as applied to claims 2-8, 10, 14, and 15 above, and further in view of O'Connor et al., US Patent 6,596,302.

The claimed invention and the invention of Smith are recited above. The claimed invention of claim 9 further comprises the polyunsaturated fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in a weight ratio of at least 2:1.

Smith further teaches that the DHA is present as DHA concentrate fish oils (page 16, line 20 and Table on page 22).

Smith differs from the claimed invention because it does not teach what other fatty acids are present in the fish oil or in what amounts.

O'Connor et al. teach that infant formulas that contain long chain polyunsaturated fatty acids (LCPs) provide enhanced neurological development of infants (col. 1, lines 10-14), and that DHA and EPA are important LCPs in the present invention (col. 8, lines

31-33). O'Connor et al. also teach that fish oils are good sources for these fatty acids, and that such fish oils are available in "high EPA" and "low EPA" varieties, the latter having a high DHA:EPA ratio, preferably at least 3:1 (col. 9, lines 13-16). O'Connor et al. further teach that supplementation of nutrient enriched formula with LCPs should preferably include DHA, and preferably should not include high levels of EPA. Low EPA fish oils are preferred for this reason if a fish oil source of DHA is employed (col. 11, lines 28-32).

It would have been obvious at the time the invention was made to use the composition of Smith with low EPA fish oil as the source of DHA as taught in O'Connor et al. to aid the cognitive development or cognitive performance of humans having an age of up to 18 years, with a reasonable expectation of success.

One skilled in the art would have been motivated to use the low EPA fish oil having the DHA: EPA ratio of at least 3:1 as taught in O'Connor et al. as the fish oil source of DHA in the composition of Smith, since the composition of Smith is directed to improving mental performance, and low EPA fish oil is the preferred source of DHA in infant formulas that provide enhanced neurological development as taught by O'Connor et al.

Response to Arguments

8. Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive.

As Applicants have not argued the merits of this rejection separately, the rejection stands for reasons stated above.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611